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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,136	01/25/2002	Jeffrey Schlom	700953-047113-C	3148

50187 7590 08/23/2005

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EXAMINER	
WHITEMAN, BRIAN A	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/057,136	SCHLOM ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-31,34-37,41-42,45-52,54-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-31,34-37,41-42,45-52,54-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Notice to comply*.

S.o.D

DETAILED ACTION

Non-Final Rejection

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/6/05 has been entered.

Claims 23-31, 34-37, 41-42, 45-52, and 54-64 are pending.

Applicant's traversal, the cancellation of claims 32, 33, 38-40, 43, 44, and 53 and the amendment to claims 23-25, 27, 34-37, 41, 45, 49-51, 54-55, and 58-64 filed on 6/6/05 is acknowledged by the examiner.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892 or form PTO-1449, they have not been considered.

Specification

The disclosure is objected to because of the following informalities: The disclosure is objected to because of the following informalities: This application contains sequence disclosures that are encompassed by the definition for nucleotide sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with requirements of 37 CFR 1.821 through 1.825 because there is a sequence listed in the specification on page 19 (Table C, repeat 5) has the incorrect SEQ ID NO. Repeat 5 has SEQ ID NO: 1, however the amino acid sequences is longer than SEQ ID NO: 1. Thus, the amino acid sequence is missing its proper SEQ ID NO and it appears that the SEQ ID NO is missing from the CRF.

A complete reply to the instant office action requires compliance with requirements of 37 CFR 1.821 through 1.825 or the response will be considered non-responsive.

Appropriate correction is required.

The disclosure is also objected to because of the following informalities: there are two pages numbered 11. The examiner reviewed the prosecution history of the instant application and could not locate an amendment indicating the renumbering of the pages in the specification.

Appropriate correction is required.

Claim Objections

Claims 23, 27 and 64 are objected to because of the following informalities: the term "instances of an altered nucleotide" is not an art acceptable term. "Instances" and "nucleotide sequence" are not equivalent terms.

Claim 46 is objected to because of the following informalities: the phrase "wherein said co-stimulatory molecule B7" one lines 1-2 of claim 46 is grammatically incorrect. Suggest amending the phrase to recite:

-- wherein said co-stimulatory molecule is B7 --. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-31, 34-37, 41-42, 45-52, and 54-64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitation 'a first nucleotide sequence encoding the amino acid sequence of SEQ ID NO: 1 as one of the tandem repeats units and a second nucleotide sequence encoding 4 to 24 copies of the amino acid sequences of SEQ ID NO: 1 as the other 4 to 24 tandem repeats units, the second nucleotide sequence comprising 4 to 24 instances of an altered nucleotide of SEQ ID NO: 2 by changing wobbled nucleotides of the codons of SEQ ID NO: 2, the 4 to 24 tandem repeat units' in amended claims 23 and 27 (and claims dependent therefrom) is not supported by the as-filed specification. There does not appear to be a written description of the claim limitation in the application as filed. See MPEP § 2163.06. Applicant cites several parts of the

instant application for support of the claimed subject matter. See page 3, lines 31-33; page 9, lines 7-12 and lines 26-32; page 13, line 34; and original claims 1 and 5. However, original claims 1 and 5 are directed to a MUC1 cDNA sequence with several tandem repeats having no modifications. Page 3 is directed to a recombinant poxvirus encoding a MUC1 fragment and using the recombinant poxvirus. Page 9, lines 7-12 is directed to promoters. Page 9, lines 26-32 is directed to using MUC1 DNA sequence from the human MUC1 cDNA sequence disclosed by Gendler et al. The cDNA sequence taught by Gendler does not support altering specific codons of the cDNA sequence taught by Gendler as recited in the limitation. There is no page 13, line 34.

"It is not sufficient for purposes of the written description requirement of Section 112 that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose." *Lockwood v. American Airlines Inc.*, 41 USPQ2d 1961, 1966 (CAFC 1997).

The limitation 'a second nucleotide sequence comprising 4 to 24 altered nucleotide sequences encoding 4 to 24 altered tandem repast, wherein each altered tandem repeat is altered from SEQ ID NO: 2 by substituting at least one codon in SEQ ID NO: 1 such the each altered nucleotide sequence is selected from the group consisting of substituting at least one of the glycines in the SEQ ID NO: 1 to serine, substituting at least one of the serines in SEQ ID NO: 1 to glycine, and substituting the valine in SEQ ID NO: 1 to leucine' in amended claim 63 is not supported by the as-filed specification. There does not appear to be a written description of the claim limitation in the application as filed. See MPEP § 2163.06. Applicant cites several parts of the instant application for support of the claimed subject matter. See page 9, lines 26-32 and

page 12, lines 6-7. However, neither page 9 nor page 12 recites the limitation. Page 9 is directed to using MUC1 DNA sequence from the human MUC1 cDNA sequence disclosed by Gendler et al. The cDNA sequence taught by Gendler does not support altering specific codons of the cDNA sequence taught by Gendler as recited in the limitation. Page 12 (absence evidence to the contrary is assumed to be the second page numbered 11) is directed to SEQ ID NO: 3.

The limitation 'encoding an immunogenic fragment comprising 6 identical tandem repeat units, the nucleic acid sequence comprising a first nucleotide sequence encoding the amino acid sequence of SEQ ID NO: 1 as one of the tandem repeat units; and a second nucleotide sequence encoding 5 copies of the amino acid sequence of SEQ ID NO: 1 as the other 5 tandem repeat units, the second amino acid sequence comprising 5 instances of an altered nucleotide sequence of SEQ ID NO: 2 by changing wobbled nucleotides of the codon of SEQ ID NO: 2, the 5 instances encoding the other 5 tandem repeat units' in amended claim 64 is not supported by the as-filed specification. There does not appear to be a written description of the claim limitation in the application as filed. See MPEP § 2163.06. Applicant cites several parts of the instant application for support of the claimed subject matter. See page 3, lines 31-33, page 4, lines 1-4, page 9, lines 7-12 and 22-32 and original claim 1. Original claim 1, page 4 (lines 1-4), and page 9 are directed to a MUC1 cDNA sequence with several tandem repeats having no modifications. Page 3 is directed to a recombinant poxvirus encoding a MUC1 fragment and using the recombinant poxvirus. See Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1326, 56 USPQ2d 1481, 1486 (Fed. Cir. 2000).

It is apparent that the applicants at the time the invention was made did not intend or contemplate making and/or using the limitation set forth in the amended claims as part of the

disclosure of their invention. There is no evidence in the specification that the applicants were possession of the limitation as set forth in the amended claims, as it is now claimed, at the time the application was filed.

Applicant's arguments filed 6/6/05 have been fully considered but they are not persuasive because for the reasons of record and because the statement "support for these amendments can be found throughout the specification" does not provide support the amended claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, acting SPE – Art Unit 1635, can be reached at (571) 272-0811.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman
Patent Examiner, Group 1635

Brian Whiteman

Notice to Comply	Application No. 10/057,136	Applicant(s) SCHLOM et al.	
	Examiner B. Whiteman	Art Unit 1635	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set in the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: Page 19 has an amino acid sequence that is mislabeled and is missing the correct SEQ ID NO.

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the specification.**

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (571) 272-2510
For CRF Submission Help, call (571) 272-2501/2583.
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